



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,399	09/17/1999	GLEND A C. DELENSTARR	10981620-1	1056
22878	7590	11/04/2003	EXAMINER	
AGILENT TECHNOLOGIES, INC. INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT. P.O. BOX 7599 M/S DL429 LOVELAND, CO 80537-0599			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/398,399	Applicant(s) DELENSTARR ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-52 and 54-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-52 and 54-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 50-52 and 54-68 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dehlinger (US Patent 5,723,320) in view of Fodor et al. (US Patent 5,445,934), Blanchard

Art Unit: 1634

et al. (*Biosensors and Bioelectronics*, Vol. 11, No. 6/7, 687-690, 1996), and Brink et al. (US Patent 5,563,034).

5. Dehlinger, column 13, discloses methods of using arrays of oligonucleotides. Such methods encompass sequencing -by-hybridization, diagnostics, and gene expression. Column 12 specifically teaches that an array may contain internal control sequences. Column 12 describes an assortment of probes that can range in lengths from 10 to 50 bases in length.

6. Dehlinger does not teach use of applicant's "background nucleic acid feature" nor the use of sequences represented by SEQ ID NOS: 05 to 32.

7. Fodor et al., column 15, discloses the synthesis of arrays of oligonucleotides that comprise up to 10^8 different sequences which, at column 25, are further defined as optionally being oligonucleotides and that these oligonucleotides can be dodecanucleotides or larger. The examiner takes notice that an array of 10^8 oligonucleotides would accommodate all possible oligonucleotides 13 bases in length (6.71×10^7 oligonucleotides). Accordingly, an oligonucleotide array comprising all possible 13-mers would, by default, comprise those sequences explicitly recited by applicant that are 13 bases or less in length.

8. Blanchard et al., teach explicitly of the production of oligonucleotide arrays that comprise all possible oligonucleotides of a given length.

9. Neither Fodor et al., nor Blanchard et al., teach the use of sequences that will not hybridize to their complement.

10. Brink et al., columns 3-4, disclose and encourage the use of control sequences. As set forth at column 3:

The problem [of background signal or noise] can be resolved by the use of Type I and Type II negative control probes described herein. These probes are analogous in almost

Art Unit: 1634

every respect to the experimental probes, except in their ability to bind the intended nucleic acid target. In addition, if there is non-specific probe binding, probe trapping, or insufficient washing, the experimental and negative control probe will allow one to accurately determine how much of the experimental signal is due to binding of the experimental probe to the target nucleic acid.

11. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to have incorporated “negative control probes” (applicant’s “background nucleic acid feature”) into an array and method of Dehlinger wherein said array had virtually every oligo of a given length (Fodor et al. and Blanchard et al.) and to have done so with the enhanced accuracy afforded by the use of control sequences (Brink et al.). In view of the motivation provided by Brink et al., and the well-developed state of the art, the ordinary artisan would not only have been highly motivated but would have also had a most reasonable expectation of success.

12. For the above reasons, and in the absence of convincing evidence to the contrary, the method of claims 50-52 and 54-67, as well as the kit of claim 68 are rendered obvious by the prior art of record.

Response to arguments

13. At page 8 of the response applicant asserts that the claimed method utilizes “background feature” (also called a “background probe,” *infra*) “that does not hybridize to its fully complementary target nucleic acid under stringent conditions, where the target nucleic acid is one that is fully complementary to the probe and therefore would be expected to hybridize to the probe. Page 6, last paragraph, of the response asserts that the claimed method does not necessarily include use of fully complementary fluorescently labeled target or that an array is employed.

Art Unit: 1634

14. At page 8 of the response received 06 February 2003 (hereinafter the response) it is asserted:

None of the references teach or suggest, either alone or in combination, such a probe as a background probe. In fact, all of the mentioned negative control probe sequences in the cited references are ones that, based on known structure and sequence, are expected not to bind to their corresponding targets.

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. As presented above, Fodor et al., teaches use of arrays that comprise the very "background feature" or "background probe" that is to be used in applicant's claimed method. It is well settled that a compound and its properties are inseparable. Accordingly, the "background probes" encompassed in the array of Fodor et al., would exhibit the same effect when used in a hybridization assay of the prior art as they would in the same assay now claimed by applicant.

15. As noted by applicant at page 6 of the response, their assay does not require that one have present as a target nucleic acid that sequence that is fully complementary to the background feature, but that the background feature needs to be present. As noted above in the body of the rejection, the array of Fodor can comprise 10^8 oligonucleotides, and as such would encompass all oligonucleotides that are 13 bases in length and would, by default, comprise those sequences explicitly recited by applicant that are 13 bases or less in length. The prior art teaches using such arrays for the detection of innumerable target nucleic acids. The detection of target nucleic acids that are not fully complementary to applicant's "background features," yet are complementary to other sequences on the array, would fairly render obvious the claimed assay, as the background features would be present and exerting their effect to reduce background.

Art Unit: 1634

16. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

17. Rejections that appeared in the prior Office action, and that were not repeated hereinabove, have been withdrawn.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

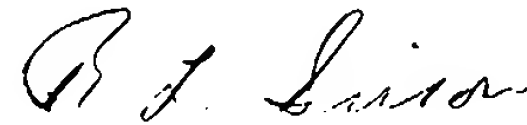
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1634

22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 02, 2003